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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,714	12/28/2001	Bernhard Eistert	KEIL/149/PC/US	1040

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ALIX YALE & RISTAS LLP  
750 MAIN STREET  
SUITE 1400  
HARTFORD, CT 06103

EXAMINER
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WEISS JR, JOSEPH FRANCIS

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 12/10/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/019,714

Applicant(s)

EISTERT, BERNHARD

Examiner

Joseph F Weiss Jr.

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Psaros (US 5765558).

In regards to claim 1, Psaros discloses a tracheal cannula (note fig 7) having a shaft (2) and a cuff (6) for blocking the tracheal cross sectional area surrounding the shaft such that a section of the shaft above the cuff has a window (44) that is covered by an air permeable membrane (46) that is fully capable and is insertable following a user undergoing a tracheotomy (See fig 7) that inherently and fully capable of being sufficiently permeable to be "sound permeable" to thus allow patient vocalization by dint of being permeable to gases just as applicant's. (Note US 6503303 noting that sound permeability does not require air permeability).

In regards to claim 2, the membrane of Psaros is made of gas permeable TEFLON, such micro-porous materials are inherently liquid water impermeable. (See e.g. US 5177996, see also TESS Reg. # 1111147)(col. 4 lines 40-45)

In regards to claim 3, Psaros discloses the membrane consisting essentially of PTFE.(col. 4 lines 40-45)

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In regards to claim 4, Psaros discloses the membrane comprising PTFE.(col. 4 lines 40-45).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Psaros.

In regards to claims 5 & 6, Psaros substantially discloses the claimed invention except for the use of "laced" or woven PTFE as the membrane material, a.k.a. Goretex.

It is noted that applicant's specification does not set forth the use of woven PTFE, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art. Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary. See e.g. 4921642

5. Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Psaros as applied to claims 1-6 above, and further in view of Muir (US 4759356).

In regards to claims 7-12, Psaros substantially discloses the instant application's claimed invention, but does not explicitly disclose a valve that opens upon inhalation & closes upon exhalation at the entrance of the cannula. However, Muir disclose such (10). The references are analogous since they are from the same field of endeavor, the respirator arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Muir and used them with the device of Psaros. The suggestion/motivation for doing so would have been to permit the patient to have improved speech while tracheotomized (Note abstract & Summary of invention). Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

6. Claims 13-18 & 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Psaros as applied to claims 1-6 above, and further in view of Abel (US 5056515).

In regards to claim 13-18, Psaros substantially discloses the instant application's claimed invention, but does not explicitly disclose the cuff connected via a line to a balloon means for inflation of the cuff and controlling cuff pressure. However, Abel disclose such (line 68, balloon means 70). The references are analogous since they are from the same field of endeavor, the respirator arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in

the art to have taken the features of Abel and used them with the device of Psaros. The suggestion/motivation for doing so would have been to insure optimal fit of the cuff to the user's trachea without damage to the tracheal tissue. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 20, the suggested device discloses the balloon means as a pilot balloon. (See Abel 70).

7. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Psaros & Muir as applied to claim 7 above, and further in view of Abel (US 5056515).

In regards to claim 7, the suggested device substantially discloses the instant application's claimed invention, but does not explicitly disclose the cuff connected via a line to a balloon means for inflation of the cuff and controlling cuff pressure. However, Abel discloses such (line 68, balloon means 70). The references are analogous since they are from the same field of endeavor, the respirator arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Abel and used them with the suggested device. The suggestion/motivation for doing so would have been to insure optimal fit of the cuff to the user's trachea without damage to the tracheal tissue. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of

design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

*Response to Arguments*

8. Applicant's arguments filed 20 Nov 03 have been fully considered but they are not persuasive.

In regards to the prior art rejections, applicant's amendment is proper and responsive but does not resolve the issues, hence the rejections are retained and modified as needed in response to applicant's amendments to the claims with a response to the arguments as noted below:

**NOTE GENERALLY:**

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Applicant's arguments do not comply with 37 CFR 1.111© because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

**NOTE SPECIFICALLY:**

The examiner concurs that applicant has cited the proper current authority for the guideposts that if followed make the language of the pre-amble limiting. It is noted that the entire text of the guideposts set forth by *Catalina* are not presented by applicant. Also the most express and clearest way to invoke pre-amble limitation, repetition of the language of the preamble in the body of the claim is absent from the claims, thus no conclusion can be made to determine if the pre-amble limitations are or are not limiting.

However, this is all much ado about very little because regardless of any possible legal merit on this issue, the fact remains that Psaros (See fig 7) meets this illusory limitation. This has been pointed out to applicant several times only to be ignored repeatedly. Therefore here is the most atomistic analysis possible and the examiner extend any apologies necessary to anyone of ordinary skill in the respiratory art who reads the following:

“Tracheostomy” by definition means the operation of opening the trachea. (See stedmans medical dictionary excerpt)

The larynx is anatomically located between the root of the tongue and the trachea. (See Alexander’s care of the patient in surgery excerpt)

Psaros expressly sets forth in col. 5 line 38 that the tube in fig 7 is a tracheotomy tube.

Hence by sheer force of logic one of ordinary skill in the respiratory arts understands instantly that the tube of Psaros is passed into an incision in the trachea and thus it is in fact below the larynx.

In regards to the issue of permeable, poor permeability is still permeability, hence it meets the plain language of the claim. Furthermore, NO is also a component of air and its permeability is something greater than poor. Applicant has in no way positively claimed a quantification of permeability, hence the argument is not persuasive.

Sound permeability does not require air permeability, hence if a membrane does have permeability to gasses as applicant sets forth his as having, they is has sound permeability for vocalization. Psaros has this, thus it inherently has sound permeability for vocalization. This remark is in response to both applicant’s 102 based arguments and 103 based arguments.

Furthermore:



In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or **in the knowledge generally available to one of ordinary skill in the art.** See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Also not the devices are not being combined, but the teachings are being combined to suggest a device, hence applicant's speculation of non-functional device is not persuasive.

Regarding the issue of "teaching away", an unspoken supposition for applicant's argument appears to be that the window applicant is using is designed/adapted etc for use as having a primary role in ventilation of the patient, i.e. handling primary flow of respiratory gases, however, this intimation from the arguments is nowhere to be found in the claim language, and limitation of the written description cannot be read into the claims except for the statutory strictures of 35 USC 112(6) or where applicant invokes specific definitions for claim language used, non of this is done. Reading the plain language of the claims and giving the language its broadest reasonable interpretation in light of the written description, the prior art anticipates and/or renders obvious the claimed invention.


**Conclusion**

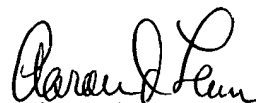
1. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6503303, Stedman's & Alexander's.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F Weiss Jr. whose telephone number is 703-305-0323. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

  
Jfweiss  
12/4/03

  
Aaron J. Lewis  
Primary Examiner